

Remarks

Rejection Under 35 U.S.C. § 112, first paragraph

Claim 34 was rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicant respectfully traverses this rejection.

Claim 34 specifies that the spacers in the brachytherapy seed or strand are elastic. The specification describes a variety of seeds and strands and notes that the strands can be formed as “chains or continuous arrays of seeds [...], with or without spacer material, flaccid, rigid, or flexible.” (page 6, lines 4-6). Examples of stands “with inert spacers” are provided in Figures 3A-3I. (page 6, lines 23-24). Figures 3A-3I are described in greater detail at page 32, line 1 until page 33, line 3. The specification also explains that spacers can be made of any biocompatible material that can be used to join two brachytherapy seeds (see page 39, lines 8-9). Examples of suitable materials include elastic materials, such as catgut and similar materials (page 39, lines 11-12), relatively flexible materials (page 39, lines 21-22), elastic polymers (page 39, lines 22-24). The specification describes forming flexible brachytherapy strands that contain elastic spacers (also referred to as “linkers”). Therefore claim 34 meets the written description requirement.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 16 and 21 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant respectfully traverses this rejection to the extent that it is applied to the claims as amended.

Claim 16 as amended specifies that the strand or seed comprises a plurality of seeds. Support for this amendment can be found in the specification at least at page 6, line 4. Claim 16 clearly indicates that a plurality of seeds is present.

Claim 21 has been canceled and rewritten as new claim 35. Thus claim 35 properly depends from prior claim 28. Therefore claims 16 and 21, as amended, are definite.

Rejection Under 35 U.S.C. § 102

Claims 1-3, 5-14, 16-21, and 24-34 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,200,258 to Slater *et al.* (“Slater”). Claims 1, 2, 4, and 15 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,247,406 to Widder *et al.* (“Widder”). Claims 1, 3, 22, and 23 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Publication No. 2002/0114763 to Glajch *et al.* (“Glajch”). Claims 1, 3, 22, 23, 27-29, and 31 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,762,950 to Yli-Urpo *et al.* (“Yli-Urpo”). Applicants respectfully traverse this rejection.

Legal Standard

The standard for lack of anticipation is one of strict identity. To anticipate a claim for a patent, a single prior art source must contain all of the claimed elements. Federal Circuit

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decisions repeatedly emphasize that anticipation is established only if the following three standards are met: (1) all the elements of an invention, as stated in a patent claim, (2) are identically set forth, (3) in a single prior art reference. *See e.g. Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 62 U.S.P.Q.2d 1865 (Fed. Cir. 2002); *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350, 60 U.S.P.Q.2d 1423 (Fed. Cir. 2001). As discussed in detail below none of the references cited by the Examiner discloses every element of the claims.

The pending claims

Three independent claims are pending. The remaining claims depend directly or indirectly from an independent claim. Each dependent claim incorporates all of the limitations of the independent claim from which it depends.

Independent claim 1 defines a brachytherapy strand or seed for implantation into a subject containing (a) a non-radionuclide imaging marker, and (b) a biocompatible carrier. Independent claim 1 also specifies that the strand or seed is elastic and has a size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10 gauge).

Independent claim 24 defines a method of making a brachytherapy strand or seed for implantation into a subject comprising mixing a biocompatible elastic carrier with a non-radioactive imaging agent to form an elastic brachytherapy strand or seed.

Independent claim 25 defines a method for administering a therapeutically active component to a target tissue in a subject, the method comprising implanting a brachytherapy strand or seed. The brachytherapy strand or seed contains (a) a non-radionuclide imaging marker, and (b) a biocompatible carrier. Like independent claim 1, claim 25 also specifies that the strand or seed is elastic and has a size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10 gauge).

The term “elastic” is defined in the specification at least at page 7, lines 26-28 and refers to a material which has the ability to recover from relatively large deformations, or withstand them, or which can be elongated to multiple times its original length without breaking.

Analysis

Slater

Slater discloses a radioactive seed. Slater describes forming radioactive seeds with different levels of radiation emission (*see abstract*). Slater’s seeds are formed of a titanium capsule (col. 4, lines 65-66), contain isotope bearing structures formed of titanium, aluminum, or glass (col. 5, lines 7-9), and contain a “relatively thick titanium tube”. (col. 5, lines 15- 16). The titanium capsule is formed by welding two halves of the capsule together. (col. 5, lines 14-15). Thus Slater’s seed is rigid, not elastic. Slater does not disclose an elastic seed. Further Slater does not disclose a strand, let alone one which is elastic. Additionally, Slater’s seeds contain radioactive materials. Slater does not disclose including a non-radionuclide imaging marker in

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the seed. Therefore independent claim 1, 24, and 25 and dependent claims 2, 3, 5-14, 16-21, and 26-34 are novel in view of Slater.

Widder

Widder discloses polymeric microspheres with magnetic particles embedded therein. (abstract) Widder does not disclose an elastic seed. Further, Widder does not disclose any strands, let alone one which is elastic. Therefore independent claim 1 and dependent claims 2, 4 and 15, are novel in view of Widder.

Glajch

Glajch discloses radiotherapy agents containing a radionuclide (*see* para. 0012). The agents are in the form of solid or porous particles, and may be incorporated into delivery systems such as tubes or seeds (para 0013). Glajch does not disclose an elastic seed. Further, Glajch's seeds contain radioactive materials. Glajch does not disclose including a non-radionuclide imaging marker in the seed. Therefore independent claim 1 and dependent claims 3, 22, and 23 are novel in view of Glajch.

Yli-Urpo

Yli-Urpo discloses a bioceramic system for delivery of a bioactive compound (abstract). The bioceramic system may be in the form of a monolithic, multi-particle system, whiskers-like or fibrous system, tablet, pill, granule, suppository or suspension (col. 4, line 65 until col. 5, line 1). Yli-Urpo lists a number of bioactive compounds at col. 4, lines 14-28, but does not include imaging agents in the list. Yli-Urpo does not disclose including a non-radionuclide imaging

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marker. Additionally, Yli-Urpo does not disclose an elastic seed. Further, Yli-Urpo does not disclose a strand, let alone one which is elastic. Finally, although Yli-Urpo broadly mentions “implanting [the system] into tissue in various ways” (col. 4, line 63), this broad disclosure is not a description of a seed or strand having a size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10 gauge), as defined by claim 1. Therefore independent claim 1 and dependent claims 3, 22, 23, 27-29, and 31 are novel in view of Yli-Urpo.

Additional Amendments to the claims

Claim 24 was amended to specify that the seed or strand is elastic. Support for this amendment can be found in the specification at least at page 7, lines 24-25. Claim 34 has been amended to more clearly refer to claim 9 from which it depends by stating that the strand or seed further comprises spacers.

Allowance of claims 1-20 and 22-35, as amended, is respectfully solicited.

Respectfully submitted,

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